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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/594,526

11/27/2006

Christophe D'Hulst

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466 7590 03/18/2010

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EXAMINER

PAGE, BRENT T

ART UNIT

PAPER NUMBER

1638

NOTIFICATION DATE

DELIVERY MODE

03/18/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/594,526	Applicant(s) D'HULST ET AL.	
	Examiner BRENT PAGE	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-13, 19, 22-26 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13, 19, 22-26 and 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/11/2010 has been entered. The addition of new claims 31-34 is hereby acknowledged. The cancellation of claims 20-21 and 27 without prejudice is hereby acknowledged. Claims 10-13, 19, 22-26, and 28-34 are pending and examined herein on the merits.

Claim Rejections - 35 USC § 112-enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-13, 19, 22-26, and 28-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

T-DNA insertion mutations can not be targeted

While the specification does disclose an Arabidopsis line DDS72, with a tDNA insert comprising SEQ ID NO:2, in which the starch grain size and/or starch content is altered, however, the insertion of line DDS72 could not be predictably repeated in another plant with any reasonable expectation of success, because the insertion was performed using random T-DNA insertion mutagenesis, therefore it appears that DDS72 is required as starting material in order to practice the invention as claimed.

Deposit

The invention appears to employ novel plant lines, namely mutant line DDS72 with a T-DNA inserted at the junction of exon 6 and intron 6. Because the starting material of the mutant plant line is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the seed is not so obtainable or available, a deposit thereof may satisfy the requirements of 35 U.S.C. 1 12. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. A deposit of the seeds of line DDS72 with an acceptable depository is required.

If the seeds will be deposited under the terms of the Budapest Treaty, then an affidavit or
declaration by the applicants, or a statement by an attorney of record over his or her signature and registration number, must also be submitted, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance

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of a patent. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

See 37 CFR 1.801-1.809.

If the deposit will not be made under the Budapest Treaty, then in order to certify that the

deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

(a) during the pendency of the application, access to the invention will be afforded to the

Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become unviable.

Claim Rejections - 35 USC § 112-scope of enablement

Applicant's arguments, see pages 9-11 of response, filed 03/11/2010, with respect to the rejection of claims 10-13, 19, 21-26 and 28-30 under 35 USC 112 first paragraph for lacking enablement over the full scope of the claims have been fully considered and are persuasive when taken together with the claim amendments. The scope of enablement rejection based on the breadth of the claims regarding the mutation of any gene has been withdrawn due to the amendment of the claims specifying the starch phosphorylase gene.

Claim Rejections - 35 USC § 112-written description

Claims 10-13, 19, 22-26, and 28-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 10, 11, 26, and 31-33 all recite the term "essentially preventing the expression of starch phosphorylase". There is no support in the specification for this phrase. The closest support can be found on page 5, wherein the specification states "it no longer or practically no longer permits expression of an active starch phosphorylation protein". However, the term "essentially preventing" or even the terms "essentially" and "preventing" separately, do not appear in the specification in even a single instance.

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Therefore the claims are directed to New Matter. Application is required to delete the New Matter from the claims.

Claims 10 and 31 recite the phrase “essentially abolish”. There is not support in the specification for this term. The claims are therefore directed to New Matter. New Matter must be deleted from the claims. It is suggested that Applicant use terms that are consistent with the terms used in the Specification.

Claims 12-13, 19, 22-25, 28-30 and 34 depend from the above claims, containing all the limitations of the parent claims and are therefore also drawn to New Matter accordingly. Removing New Matter from the parent claims would obviate this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-13, 19, 22-26, and 28-30 remain and claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Critchley et al (2001 The Plant Journal 26:89-100) and in view of Kossman et al (US patent 6686514). The claims are rejected for the reasons of record in the office actions mailed out on 01/22/2009, 11/12/2009, as well as the reasons set forth below.

The claims are drawn to a method for increasing the size of starch grains and/or starch content of a plant or plant part wherein a starch phosphorylase gene is inactivated by inserting nucleotides in the gene coding for the endogenous starch phosphorylase, the transformed plants, plant cell and seed therefrom.

Critchley et al teach the disruption of a starch biosynthesis enzyme gene by random T-DNA insertion (see page 90, 2nd column, 2nd paragraph, for example) and the screening of starch phenotypes including starch accumulation and the affect of this mutation on starch phosphorylase (see page 92, 3rd paragraph for example).

Critchley et al do not teach the inactivation of starch phosphorylase.

Kossman et al teach the transformation of maize with a nucleic acid molecule in antisense orientation wherein the expression of starch phosphorylase is reduced (see claims 1-14), and plants, host cells, and plant propagation material which includes seeds (see paragraph 31 under Summary of Invention).

One of ordinary skill in the art, based on the findings of Critchley et al, would have recognized T-DNA insertional mutagenesis as an option for inactivating a starch phosphorylase and would have reasonably expected said inactivation to result in the plants taught by Kossman et al.

Given the state of the art and the disclosures by Critchley et al and Kossman et al, it would have been obvious to one of ordinary skill in the art to modify the method of screening for increased starch accumulation using T-DNA insertional mutagenesis as taught by Critchley et al to study the effect of switching off starch phosphorylase as taught by Kossman et al to screen for increased starch accumulation. One of ordinary

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skill in the art would have been motivated to do so because starch phosphorylase has been identified as an enzyme that would modify starch content by both Kossman et al and Critchley et al and modified forms of starch are in demand in many industrial applications as discussed by Kossman et al in the background of Invention.

Applicant's arguments filed 03/11/2010 have been fully considered but they are not persuasive.

Applicants urge that Kossman et al firstly only teach a reduced activity of phosphorylase and not an "essentially" complete inactivation of starch phosphorylase (see pages 12-13 of response) and secondly that Kossman et al does not suggest that inactivating starch phosphorylase could induce both an increase in the size of the starch grains and an increase of the starch content (see page 13 of response).

This is not persuasive because Kossman et al state "The cells of the invention preferably show a reduction in the amount of transcripts encoding a protein of the invention when compared to corresponding non-transformed cells, whereby the reduction is preferably at least 30%, more preferably at least 50%, even more preferably at least 70% and most preferably at least 90%" (see paragraph 42 under Summary of Invention). In addition to stating that most preferably the reduction is at least 90% reduced, it is noted that this includes even 100% reduced transcripts. Furthermore, Applicants do not specify what "essential" complete inactivation means. While stating that it "no longer or practically no longer permits expression of an active starch phosphorylase protein", practically no longer permitting expression could be a reduction by 90% of the transcript absent evidence to the contrary or a further definition that

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excludes this possibility. Additionally, the phenotypes associated with switching off starch phosphorylase are properties that necessarily follow when said gene is switched off. Kossman et al teach switching off the starch phosphorylation gene and therefore any phenotype associated with this would naturally follow whether explicitly stated by Kossman or not. The only difference between Kossman et al and the current invention is the mode by which the gene is switched off. Given the multiple methods cited by Kossman and the disclosure by Critchley et al, it would have been obvious to one of ordinary skill in the art that T-DNA insertion was a mode readily available to switch off the starch phosphorylase gene.

Applicants urge that one would not have been motivated by Critchley et al to inactivate starch phosphorylase (see pages 13-14 of response).

This is not persuasive because Applicants are arguing the references individually rather than as a whole. Kossman et al provides motivation to inactivate starch phosphorylase by teaching the inactivation of starch phosphorylase. One must ignore the teachings of Kossman et al to not derive a benefit from inactivating starch phosphorylase given the unique starch content profile expected by Kossman et al. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

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Applicants urge that Smith et al teach that a loss of starch phosphorylase expression would have no general impact on carbohydrate metabolism in leaves (see page 14 of response).

This is not persuasive in view of Kossman's expectation of an altered starch phenotype and also given that starch is primarily harvested from maize grain, not leaves.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Examiner, Art Unit 1638